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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,491

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Sean P. McCormack

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EXAMINER

BALL, JOHN C

ART UNIT

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1759

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,491	Applicant(s) MCCORMACK ET AL.	
	Examiner J. CHRISTOPHER BALL	Art Unit 1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8,9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/06/2010</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-3,6,8,9,11-19,21,22,24-26,29-33,36,37,39-41,43-46,49-57,61-65,68 and 71-76.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-3,6,21,22,24-26,29-33,36,37,39-41,43-46,49-57,61-65,68 and 71-76.

DETAILED ACTION

Summary

1. This Office Action is based on the Amendment filed with the Office on December 8, 2010, regarding the McCORMACK *et al.* application.
2. Claims 1-3, 6, 8, 9, 11-19, 21, 22, 24-26, 29-33, 36, 37, 39-41, 43-46, 49-57, 61-65, 68, and 71-76 are currently pending, and claims 8, 9, and 11-19 have been fully considered. Claims 1-3, 6, 21, 22, 24-26, 29-33, 36, 37, 39-41, 43-46, 49-57, 61-65, 68, and 71-76 are withdrawn from consideration as being drawn to non-elected inventions.

Information Disclosure Statement

3. The information disclosure statement filed December 8, 2010, fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the foreign patent document, WO 03/106961 A2, listed therein has not been considered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 8, 9, and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over WRIGHTON et al. (US 5,223,117).

Regarding claim 8, WRIGHTON discloses a pH sensor (Col. 2, line 9) comprising:

a working electrode (12, Figures 1a & 1b) comprising carbon (Col. 13, line 45 & Col. 14, lines 10-13) modified with a chemical sensitive redox active material (Col. 13, lines 45-46); and

a counter electrode (14, Figures 1a & 1b),

wherein the ratio of the surface area of the working electrode to the surface area of the counter electrode is $1:10^2 - 10^3$ (Col. 3, lines 51-53).

WRIGHTON does not explicitly teach the surface area of the working electrode to the surface area of the counter electrode is in the range from 1:10 to 10:1.

However, it has been held where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)).

Regarding claim 9, WRIGHTON teaches the surface area of the working electrode is $250 \mu\text{m}^2$ ($100 \mu\text{m}$ long \times $2.5 \mu\text{m}$ wide; Col. 5, lines 39-40).

Regarding claim 11, WRIGHTON discloses a pH sensor (Col. 2, line 9) comprising:

a working electrode (12, Figures 1a & 1b) comprising carbon (Col. 13, line 45 & Col. 14, lines 10-13) modified with a chemical sensitive redox active material (Col. 13, lines 45-46); and

a counter electrode (14, Figures 1a & 1b),

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wherein the surface area of the working electrode is $250\ \mu\text{m}^2$ ($100\ \mu\text{m}$ long \times $2.5\ \mu\text{m}$ wide; Col. 5, lines 39-40).

WRIGHTON does not explicitly teach the surface area of the working electrode is in the range from $500\ \mu\text{m}^2$ to $0.1\ \text{m}^2$.

However, it has been held where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)).

Regarding claim 12, WRIGHTON teaches the surface area of the working electrode to the surface area of the counter electrode is $1:10^2 - 10^3$ (Col. 3, lines 51-53).

WRIGHTON does not explicitly teach the surface area of the working electrode to the surface area of the counter electrode is in the range from 1:5 to 3:1.

However, it has been held where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the

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prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)).

Regarding claim 13, WRIGHTON teaches the surface area of the working electrode is $250\text{ }\mu\text{m}^2$ ($100\text{ }\mu\text{m}$ long \times $2.5\text{ }\mu\text{m}$ wide; Col. 5, lines 39-40).

WRIGHTON does not explicitly teach the surface area of the working electrode is in the range from 0.5 mm^2 to 10 mm^2 .

However, it has been held where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (*Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984)).

Regarding claim 14, WRIGHTON teaches the chemically sensitive redox active material is sensitive to a change in pH (Col. 4, lines 30-35).

Regarding claim 15, WRIGHTON teaches the carbon is modified by derivatisation via physical adsorption of the chemically sensitive redox active material (Col. 4, lines 57-60).

Regarding claim 16, WRIGHTON teaches the working electrode further comprises at least a chemically insensitive redox active material (Col. 4, lines 23-25).

Regarding claim 17, WRIGHTON teaches "one or more redox reagents" that are chemically sensitive to the analyte (Col. 4, lines 30-32), which implies that chemically sensitive redox active material may comprises more than one different compound (e.g., Col. 4, lines 33-35).

Regarding claim 18, WRIGHTON teaches "one or more redox reagents" that are chemically sensitive to the analyte (Col. 4, lines 30-32), which implies that chemically sensitive redox active material may comprises more than one different compound (e.g., Col. 4, lines 33-35). WRIGHTON additionally teaches the working electrode comprises a redox material that is insensitive to change in pH (i.e., the analyte; Col. 4, lines 23-25). WRIGHTON states "[w]hat qualifies as a suitable reference redox reagent can vary from application to application or medium to medium" (Col. 4, lines 27-29).

WRIGHTON does not explicitly teach the working electrode comprising two insensitive redox active materials.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art, given the suggestion that the suitable reference redox reagent (i.e., the insensitive redox active material of the working electrode) may

vary per the application and medium to try utilizing two insensitive redox active materials in an effort to optimize the response of the described invention of WRIGHTON.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over WRIGHTON et al. (US 5,223,117) as applied to claims 8, 9, and 11-18 above, and further in view of an article by PANDURANGAPPA et al. ("Homogeneous chemical derivatisation of carbon particles: a novel method for functionalizing carbon surfaces", THE ANALYST, vol. 127, no. 12, Dec. 2002, p. 1568-1571), submitted to the Office on an Informational Disclosure Statement.

WRIGHTON teaches the limitations of claims 8 and 14, as outlined above.

WRIGHTON teaches explicitly as chemically sensitive redox active materials compounds that undergo reversible chemical reaction when subjected to cyclic voltammetry (Col. 4, lines 33-35), but does not make mention of a chemically sensitive redox active material that undergoes irreversible chemical reaction when subjected to cyclic voltammetry.

However, PANDURANGAPPA discloses use of an electrode with a chemically sensitive redox active material that is 4-nitrobenzenediazonium ("3.2 Chemical reduction of 4-nitrobenzenediazonium tetrafluoroborate in the presence of carbon powder" section, p. 1569), which has a proton dependent electrochemistry (Scheme 2b) and would therefore be pH sensitive. As a nitro

group-containing compound, it undergoes irreversible chemical reaction when subjected to cyclic voltammetry.

At the time of the present invention, it would have been obvious to one of ordinary skill in the art that substitution of a known element, the chemically sensitive redox active materials taught by WRIGHTON, with another known element, 4-nitrobenzenediazonium as taught by PANDURANGAPPA, would have yielded predictable results (*KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007)).

Response to Amendment

8. The declaration under 37 CFR 1.132 filed December 8, 2010, is insufficient to overcome the rejection of claims 8, 9, and 11-19 based upon the prior art reference, WRIGHTON et al., as applied under 35 USC 103(a) set forth in the last Office action because: In the declaration, Dr. Wildgoose details the infeasibility of forming a thiol-containing self-assembled monolayer on a carbon surface as is the state of the art in forming such SAM layers on gold surfaces (item #5, Wildgoose declaration). Therefore, Dr. Wildgoose concludes that one of ordinary skill in the art would not consider forming a pH sensor comprising a carbon working electrode modified by a redox active species given the teachings of WRIGHTON (item #6, Wildgoose declaration). The Examiner would agree with Dr. Wildgoose's conclusion if the WRIGHTON reference taught only what is

delineated in the declaration. However, WRIGHTON teaches more than what amounts to a preferred embodiment, specifically that thiol-containing self-assembled monolayer are not the only redox active species contemplated by WRIGHTON. WRIGHTON also explicitly recites electrodeposited redox reagents (Col. 5, line 1) as possible for use. Therefore, the argument presenting in the Wildgoose declaration is not persuasive in overcoming the previously applied 103(a) rejections.

Response to Arguments

9. Applicant's arguments filed December 8, 2010, have been fully considered but they are not persuasive. Applicant points to a preferred embodiment disclosed by WRIGHTON et al. of a gold or platinum electrode with a self-assembled layer of thiol reagents as the redox material (Remarks, p. 15) to assert WRIGHTON does not teach the limitations of the instant claims. The Applicant argues that the teachings of WRIGHTON do not lead one of ordinary skill in the art to the recited limitations in the instant claims as carbon working electrodes do not form spontaneous self-assembled layer with thiol reagents (Remarks, p. 16). Applicants further assert that carbon is not disclosed by WRIGHTON as a working electrode, but only as a counter electrode material, and carbon's inclusion among other electrode materials was "simply . . . a clerical error" (Remarks, p. 16).

However, the argument put forth by Applicant unfairly reduces the entirety of WRIGHTON down to one described preferred embodiment. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments (*In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments (*Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989)). WRIGHTON discloses, as examples, both spontaneous self-assembling molecules and electrodeposited redox reagents as surface confinable reagents. Additionally, there is no evidence that carbon as recited in claim 6 of WRIGHTON is a “clerical error”, as asserted by Applicant. While one of ordinary skill in the art may have not expected success in forming a sensor comprising a carbon working electrode and a thiol-based self-assembled monolayer, this would not preclude the alternative redox reagents, *e.g.*, an electrodeposited redox reagent, from being coupled with a carbon working electrode with an expectation of success. Therefore, the previous rejections of the claims are maintained.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone

number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 9 am to 5 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa Neckel can be reached on (571) 272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCB
02/08/2011

/Ula C Ruddock/
Supervisory Patent Examiner, Art Unit 1729